REMARKS/ARGUMENTS

Amendments to the Claims:

Claims 1-10 are present in the application. Claims 1-5 and 7-9 are amended. Claim 10 is canceled. New Claims 11-20 are added.

Claim 1 is amended to provide that the marker consists of a predetermined amount of sucrose polyester comprising sucrose behenate. Support is from Claim 2.

Claim 2 is amended to correct antecedent bases and to delete "preferably" ranges.

Claim 3 is amended to provide that the composition comprises dietary fat at the specified level, and further comprises protein and carbohydrate at the specified levels.

Claim 4 is amended to delete the preferred features, and to correct and provide antecedent bases.

Claim 5 is amended to delete the "preferably" forms and ranges; to provide that the marker consists of sucrose polyester comprising sucrose behenate (support from Claim 2 and Claim 7); to identify the subject as one under diagnosis for malabsorption of dietary fat by the digestive tract of the subject or an impairment of dietary fat digestion in the subject (support in the preamble); and to correct and provide further antecedent bases regarding measuring the amount of sucrose polyester.

Claim 7 is amended to correct antecedent basis, to delete "preferably" ranges and to provide that the amount of sucrose behenate is based upon the weight of the dietary fat. Support is in para. [0033].

Claim 8 is amended to replace the preferably phrase with the selection of either the day or each of the two consecutive days following ingestion of the test meal. The claim is definite, despite providing for one or the other selection.

Claim 9 is amended to delete the "preferably" forms of the colorant.

New Claim 11 depends from method Claim 2 and provides the amount of sucrose behenate by weight of the total of dietary fat and sucrose polyester. Support is at para [0009].

New Claim 12 depends from composition Claim 4 and identifies the colorants. Support is from original Claim 4.

New Claim 13 depends from method Claim 5 and provides that the sucrose polyester consists of sucrose behenate. Support is at para. [0010].

New Claims 14 and 15 depend from method Claim 13 and 5, respectively, and provide that the step of measuring the amount of sucrose polyester consists of measuring the amount of sucrose behenate in the fecal sample. Support is at para. [0010].

New Claim 16 depends from method Claim 5 and provides that the test meal is in liquid form. Support is from original Claim 5.

New Claim 17 depends from method Claim 5 and provides that the test meal comprises 5 to 60% dietary fat, by weight. Support is from original Claim 5.

New Claim 18 depends from method Claim 7 and provides that the provided test meal comprises 0.1% to 10% sucrose behenate by weight of the dietary fat. Support is from original Claim 7 and para. [0033].

New Claim 19 depends from method Claim 18 and provides that the test meal further comprise a colorant, as previously supported in original Claim 9.

New Claim 20 depends from method Claim 9 and identifies the colorants. Support is from original Claim 9.

Objection to the Abstract

The Examiner rightly notes that the form of the Abstract requires correction. The Abstract page is replaced with a new Abstract page.

Rejection of claims under 35 USC 112

The examiner rejects Claims 1, 3-6 and 8-9 under 35 USC 112, first paragraph, for lack of enablement for non-absorbable fat other than sucrose polyesters.

Applicants request withdrawal of the rejection in view of the amendments made to Claims 1 and 5 herein.

The examiner rejects Claims 1-9 under 35 USC 112, second paragraph.

Claim 1 is rejected for identifying sucrose polyester as a non-absorbable fat, while it is well-known in the art to be a synthetic, fat-like material or fat substitute; Claims 2, 4, 5 and 7-9 are rejected for use of "preferably" clauses; Claim 4 is also rejected for lack of antecedent basis for "fecal matter" and "the sample"; and Claim 5 is also rejected for "the non-absorbable fat marker".

Applicants thank the Examiner for pointing out these matters, and request withdrawal of the rejections in view of the aforementioned amendment made to claims herein which render the same moot.

Rejection of claims under 35 USC 101

Claim 10 was rejected for claiming a use without steps.

Applicants thank the Examiner for pointing out this matter, and request withdrawal of the rejections in view of the cancelation of Claim 10.

Rejection of claims under 35 USC 102

Claims 1-3, 5-6 and 8 are rejected as anticipated (35 USC §102(b)) by Mattson (US 3,600,186).

With respect to composition Claims 1-3, Applicants request reconsideration, in view of the amendment to Claim 1 providing that the marker consists of a predetermined amount of sucrose polyester comprising sucrose behenate.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference (*Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). The reference also must show the identical invention in as complete detail as is contained in the claim. (*Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989)).

Mattson discloses certain fatty acid ester compounds that are not digested or absorbed to the same extent as ordinary triglyceride fat. The fatty acid chains of the fatty acid ester compounds are generally "esterified with a fatty acid having from about 8 to about 22 carbon atoms." (col 2 lines 70-72). The highly preferred fatty acid esters contain about 14 to about 18 carbon atoms (col 4 lines 23-26). The sugars can be one of many monosaccharides and disaccharides, including preferred alcohol moieties of xylitol, sorbitol, glucose, erythrose and sucrose (col 2 lines 49-68). Mattson identifies several specific fatty acid ester compounds (col 4 lines 9-31); however the compound sucrose behenate is not specifically named or disclosed expressly or inherently in Mattson.

Mattson also disclosed a single set of experiments relating to test compositions that are fed to subjects. The test compositions contained only oleic (C18) fatty acid esters and do not contain behenic esters (see Table II).

Therefore, the disclosure Mattson does not describe a test composition containing sucrose behenate, and does not anticipate the claims.

With respect to method Claims 5-6 and 8, Applicants traverse. Mattson's analyses (total fatty acid by the Saponification Procedure) do not appear to distinguish between the fatty acids contributed by triolein and by the fatty acid ester test materials. Mattson is not separately measuring the amount of the dietary fat and the amount of the sucrose polyester recovered in the fecal sample, as required by Applicants' amended claims. Nevertheless, to further distinguish the method claims from Mattson, Claim 5 has been amended to provide that the sucrose polyester comprises sucrose behenate, which also is not expressly or inherently disclosed, *per se* or in a test composition.

Claims 1-2 are rejected as anticipated (35 USC §102b) by Young (US 5,085,884)

Applicants traverse.

Young teaches a fat composition consisting of ordinary digestible fat and a non-absorbable fat consisting of both a liquid (MP < 37°C) polyol polyester, and a solid polyol polyester (MP > 37°C). Young also teaches "low moisture foods" including potato chips containing the above fat composition. While the food compositions of Young may be low calorie and may "comprise" the fat composition, there is no express description or teaching in the Young patent that the amounts of digestible fat and non-digestible fat marker in the food compositions of Young are in "pre-determined amounts", as required by the Applicants' claims. Young teaches that the potato chips have the fat composition applied in a variety of ways, including immersing, dipping, soaking, spraying, blowing, pouring, etc, etc, and that the fat composition is typically absorbed into the interior of the food. (see column 19 lines 41-61].

Consequently, Young fails to disclose expressly or inherently each element and feature of the invention as claimed.

Rejection of claims under 35 USC 103

Claims 7 and 10 are rejected as obvious (35 USC §103(a)) over a combination of Mattson and Young.

The Examiner suggests that it would be obvious to take the sucrose behenate of Young and put it into the FAT BALANCE EXPERIMENT done by Mattson at col 5.

First, neither Young nor Mattson disclose or suggest, or make obvious, a method for "diagnosing malabsorption of dietary fat by the digestive tract of the subject, and impairment of dietary fat digestion in the subject". Mattson addresses the reduction in absorption of the fatty acid esters useful as a fat substitute, and any effect that the fatty acid esters might have on the digestion and absorption of normal triglycerides. Young is concerned with reduced calorie fat and food compositions. Neither Mattson nor Young are concerned with, or make any disclosure or suggestion for, use of sucrose polyester in a test for malabsorption of normal dietary fats. Mattson determines that normal triglycerides (triolein) have high, substantially normal coefficients of absorbability in combination with the fatty acid esters in the test compositions (Tables II and III).

Second, neither Mattson nor Young disclose or suggest, or make obvious, a method where the amount of dietary fat and the amount of sucrose polyester (including sucrose behenate) in the fecal matter are each measured (in step d).

Therefore, the alleged combination does not teach or make obvious every feature and limitation of the claims, and would not lead one of ordinary skill to predict the use of the claimed composition for the claimed use.

Claims 4 and 9 are rejected as obvious (35 USC §103(a)) over a combination of Mattson and Janghorbani (US 6,006,754).

Janghorbani teaches a colorant added to a composition for measurement of fat absorption. The colorant is used to identify fecal matter produced by the consumed composition. The composition includes labeled dietary fat and a non-absorbable, non-fat marker. The amounts of any labeled dietary fat and the non-fat marker are measured to identify the amount of dietary fat absorbed.

In view of the arguments presented herein, dependent Claims 4 and 9 are likewise non-obvious and patentable.

Supplemental IDS

Applicants have submitted a supplemental IDS on November 3, 2008 which discloses Fallat, R. W., C. J. Glueck, R. Lutmer, and F. H. Mattson ("Fallat et al"), entitled "*Short term study of sucrose polyester a nonabsorbable fat-like material as a dietary agent for lowering plasma cholesterol*", Am. J. Clin. Nutr. 29: 1204-1215, 1976.

Fallat et al discloses a study of sucrose polyester as a cholesterol-lowering agent. The test composition comprises ordinary triglycerides and sucrose polyesters (SPE), which do not include behenic acids. The sucrose polyesters used for the study were obtained from a blend of partially hydrogenated soybean oil (iodine value 107) and completely hydrogenated soybean oil (iodine value 8) (page 1205, right column, lines 2-6). The analysis of fatty acids in the fecal samples presented a challenge due to separation of liquid portions of the sample, which needed to be processed by freeze drying to a powder that then could be homogenized before sampling and analysis (page 1207, right column, *Analysis of stools*). An extracted lipid fraction was analyzed by gas-liquid chromatography for total fatty acid species, and by high pressure gel permeation chromatography for the content of SPE (page 1207, right column, 2nd full paragraph, last 7 lines). Fallat et al reports the results of these analyses in Table 6, which showed that the addition or substitution of SPE for normal dietary fat did not change the level of the non-SPE lipids in the stool (page 1211, left column, lines 6-8, and Table 7). Fallat et al is not concerned with, and does not suggest, a method for measuring total dietary fat absorption by the digestive tract of a subject, useful for diagnostic testing for diagnosing malabsorption of dietary fat by the digestive tract of the subject, and impairment of dietary fat digestion in the subject.

Applicants contend therefore that neither Fallat et al, nor a combination of Fallat et al and Mattson and/or Young, disclose, suggest or make obvious each and every element and feature of the invention as claimed.

CONCLUSION

Applicants believe that a complete response to the outstanding action has been made, and that the amended claims are patentable over the prior art of record.

Respectfully submitted,

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